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October 24, 2002

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Marjorie Shulman
Office of Device Evaluation
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Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

VIA FEDERAL EXPRESS

Re: Sirona Dental Systems 513(e) Reclassification Petition for CEREC Ceramic Dental Restoration Systems

Dear Ms. Shulman,

On behalf of my client, Sirona Dental Systems GmbH, I hereby request that the 513(e) Reclassification Petition for CEREC Ceramic Dental Restoration Systems be converted from a request for Class I exempt status to a request for Class II exempt status.

Should you have any questions or need further information, please contact me by telephone at 508-643-0434, extension 148, by facsimile at 508-643-2237, or by e-mail at heyer@mdci.com.

Sincerely,

Cynthia Sinclair

for Sheila Hemeon-Heyer, J.D., RAC
Senior Staff Consultant

SHH/lf

ISO 9001 Certified
FS #40735

Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760
Tel: 508/643-0434
Fax: 508/643-2237
www.mdci.com

02P-0494

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	Coordination		Justify		

REMARKS

The filing date should be 10/25 - the date we received the letter changing this from a reclassification petition to a class II exemption petition.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/ Post)	Room No. - Bldg.	Phone No.
joseph sheehan HFZ-215	240W/1350	827-2974

5041-103

OPTIONAL FORM 41 (Rev. 1-94)
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MDCI
MEDICAL DEVICE CONSULTANTS, INC.

August 15, 2002

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

VIA FEDERAL EXPRESS

Re: 513(e) Reclassification Petition for CEREC® Ceramic Dental Restoration Systems

Dear Sir/Madam:

Enclosed please find the original and two copies of a reclassification petition for the *CEREC® Ceramic Dental Restoration Systems* submitted pursuant to Section 513(e) of the Federal Food, Drug and Cosmetic Act. This 513(e) Petition complies with the content and form specified in 21 CFR 860.123 and is submitted on behalf of our client, Sirona Dental Systems GmbH, Bensheim, Germany.

Should you have any questions or require additional information, please do not hesitate to contact me by telephone at (508) 643-0434, extension 148, by facsimile at (508) 643-2237 or by e-mail at heyer@mdci.com.

Sincerely,

Sheila M. Hemeon-Heyer

Sheila Hemeon-Heyer, JD, RAC
Senior Staff Consultant

SHH/lf
Enclosures

513(e) Reclassification Petition
for
Sirona Dental Systems GmbH
CEREC® Ceramic Dental Restoration Systems

August 15, 2002

Sirona Dental Systems GmbH
Fabrikstraße 31
D-64625 Bensheim
Germany

513(e) Reclassification Petition
for
Sirona Dental Systems GmbH
CEREC® Ceramic Dental Restoration Systems

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513(e) Reclassification Petition
for
Sirona Dental Systems GmbH
CEREC® Ceramic Dental Restoration Systems

1. PETITIONER NAME AND ADDRESS

1.1 Manufacturer

Sirona Dental Systems GmbH
Fabrikstraße 31
D-64625 Bensheim
Germany

1.2 Consultant/Contact

Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760
Telephone: 508-643-0434
Facsimile: 508-643-2237
Primary Contact: Sheila Hemeon-Heyer, extension 148
Secondary Contact: James R. Veale, extension 106

2. TYPE OF DEVICE FOR WHICH RECLASSIFICATION IS REQUESTED

Reclassification is being requested for data acquisition systems used in the computer-aided design and milling of dental restorative prosthetic devices. The data acquisition systems include a method of scanning and a computer system with software to process the scanned image for use by a CAD/CAM milling system that generates the actual restoration. Two types of data acquisition scanning devices have been cleared by FDA under 510(k) Premarket Notifications. The first device is a 3-D camera that can be used either for optical scanning of the teeth directly or to scan a model or impression of the teeth. The second device is a laser scanner that is only used to scan a model or impression of the teeth [see below for 510(k) numbers]. In both techniques, the data acquisition device is used to record the topographical characteristics of the scanned teeth or impression and provide this data to the CAD/CAM milling system that is used to design and manufacture the restoration.

Please note that FDA has previously determined that CAD/CAM systems used to produce dental restorations are not regulated as medical devices (see FDA letter regarding K884166, APPENDIX A). Therefore, the only portion of the system described above currently regulated as a medical device is the data acquisition unit (i.e., the camera or laser scanner and associated computer hardware and software used for data acquisition).

The petitioner currently markets the CEREC® family of ceramic dental restoration systems, which include the 3-D scanning camera and/or laser scanner. These systems have been found substantially equivalent under the following premarket notifications:

3-D scanning camera

Cerec 2:	K950299
Cerec 2 Crown Software:	K972276
Cerec 3:	K994172

Laser scanner

Cerec Scan and Cerec Inlab: K012517

The information provided in this reclassification petition will be specific to the CEREC® family of devices.

3. ACTION REQUESTED BY PETITIONER

Data acquisition systems used in the computer-aided design and milling of dental restorative prosthetic devices are currently reviewed under 21 CFR 872.3660, Impression Material, Class II, Product Code ELW. The petitioner requests that these types of devices be separated from the impression material type of devices and placed in a new classification. Please note that we are not requesting that the classification of Impression materials be changed. We are proposing that a new classification category be created for the data acquisition systems, as follows:

Section 872.xxxx: Data acquisition devices for computer-aided design and milling of dental restorations

(a) *Identification*: A data acquisition device for computer-aided design and milling of dental restoration is a device used to record the topographical

characteristics of teeth, dental impressions, or dental molds by analog or digital methods for use in the computer-aided design and milling of dental restorative prosthetic devices. These systems may consist of a camera, scanner or equivalent type of sensor and a computer with software.

(b) *Classification*: Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

4. SUPPLEMENTAL DATA SHEET

The completed supplemental data sheet for the CEREC® Ceramic Dental Restoration Systems is provided in APPENDIX B of this 513(e) Petition.

5. CLASSIFICATION QUESTIONNAIRE

The completed classification questionnaire for the CEREC® Ceramic Dental Restoration Systems is provided in APPENDIX C of this 513(e) Petition.

6. BASIS FOR DISAGREEMENT WITH PRESENT CLASSIFICATION

The petitioner believes that the classification for the data acquisition devices for computer-aided design and milling of dental restorations should be separated from that of impression materials in 21 CFR 872.3660 because the two products are inherently different and have different risk profiles. Impression materials were classified in Class II because of concerns about the safety of the materials. The only risks for impression materials identified by FDA and the advisory panel were adverse tissue reactions if the materials were not biocompatible and tissue trauma if the materials were not of adequate quality (see Proposed Rule for Classification of Impression Materials in APPENDIX D). None of these risks apply to the data acquisition systems used for computer-aided design and milling of dental restorations.

The potential risks associated with use of the dental data acquisition cameras and scanners are discussed in paragraph 9 below. The risks to the patient from these data acquisition systems are minor since there is no direct contact by the patient with any of the components of the device, except possibly with the 3-D camera when it is placed in the oral cavity to obtain an image. The minor risks associated with this device are similar to those inherent in other dental devices that are classified in Class I and exempt from premarket notification, such as intraoral dental drills (872.4130), dental handpieces (872.4200) and dental operative unit accessories

(872.6640). Please note that intraoral cameras used to display images of the teeth are currently regulated in the category of dental operative units and accessories.

In addition, these types of devices are not life-supporting or life-sustaining, are not intended for a use that is of substantial importance in preventing the impairment of human health, and do not present a potential unreasonable risk of illness or injury.

For these reasons, the petitioner believes that data acquisition systems for computer-aided design and milling of dental restorations are more appropriately regulated as Class I devices, exempt from 510(k) Premarket Notification, because the general controls for medical devices specified in the Federal Food, Drug and Cosmetic Act (Act), including adulteration (section 501), misbranding (section 502), registration and listing (section 510), banned devices (section 516), notification and other remedies (section 518) and general provisions (section 520) are sufficient to provide reasonable assurance of the safety and effectiveness of these devices for their intended use.

7. How Proposed Classification Will Provide Reasonable Assurance of the Safety and Effectiveness of the Device

Given the low level of risk associated with these devices, the proposed classification will provide reasonable assurance of the safety and effectiveness of the device. The device will still be subject to the general controls of the Act listed in paragraph 6 above. Manufacturers of these types of devices will still be required to register their establishment and list these devices with the FDA, and will be required to manufacture these devices in compliance with FDA's Quality System Regulations.

In addition, the devices will be prescription devices for sale and use by licensed practitioners. Trained dentists or dental assistants will use the camera to acquire the data necessary to produce the dental restoration. Trained dental technicians will use the laser scanner to scan the model of the tooth. The restorations will be produced by trained dental technicians and fitted by dentists. The dentist will be able to recognize any problems with the fit of the restoration and will be able to adjust the fit as appropriate.

8. DATA AND INFORMATION UNFAVORABLE TO PETITIONER'S POSITION

The petitioner is not aware of any data or information that is unfavorable to the position supporting the reclassification of these devices to Class I, exempt. Since 1994, approximately 6000 CEREC® 2 Acquisition Units, 2724 CEREC® 3 Acquisition Units, and 655 CEREC® Scans have been sold worldwide. The petitioner has received no complaints of injuries or malfunctions that could result in injuries concerning the CEREC® devices. In addition, there have been no MDRs filed for these types of devices and there are no known reports of injuries in the literature relating to these types of devices.

9. NEW INFORMATION TO SUPPORT 513(E) RECLASSIFICATION PETITION

The CEREC family of ceramic dental restoration systems, including the CEREC 2, CEREC 3, CEREC Scan, and CEREC InLab, were previously reviewed by the FDA in the 510(k) Premarket Notifications listed in paragraph 2 above. The 510(k)s described both the acquisition unit and the CAD-CAM portion of the system, even though the CAD-CAM portion was not considered to be a medical device subject to the regulations of the Act.

Two types of data acquisition devices have been described in the CEREC 510(k)s. The CEREC 2 (K950299 and K972276) and CEREC 3 (K994172) 510(k)s described the 3-D scanning camera, while the CEREC Scan and InLab 510(k) (K012517) described the laser scanner. The 3-D scanning camera can be used for direct scanning of the teeth or for scanning a model or impression, while the laser scanner is used only for scanning a model or impression. Prior to optical scanning, the teeth, model or impression must be prepared by applying an optical brightener consisting of an adhesive liquid agent and contrast powder. These products are reviewed under separate 510(k)s and are not intended to be included in this reclassification petition.

The laser scanner in the CEREC system is located within the milling unit and consists of a low power (250 μW) 670 nm Class II laser diode. Neither the operator nor the patient is exposed to the laser during use. When installed in the milling unit, the protective housing reduces accessible emissions of the laser scanner to Class I levels as defined in 21 CFR 1040.10(b)(5). A safety interlock causes the laser radiation to be disabled when the milling chamber door is open, thus preventing the operation of the laser scanner without the protective housing in place. There are no

maintenance procedures that require the laser to be operational while the protective housing is removed. The sensor power is adjusted in the factory, after which the sensor casing is closed, and there are no controls or adjustments required by the user for operation or maintenance of the laser.

Both the 3-D scanning camera and the laser scanner are used in conjunction with the CEREC software on either a built-in or stand-alone computer. Data from the acquisition device undergoes analog to digital conversion and is transferred to the PC for the design stage. The output of the design stage is the data required for the milling process. The CEREC software has been designated as MINOR concern and includes functions required to design and manufacture the restorations, such as displaying the scanned image of the tooth, impression, or model on the LCD monitor, designing and editing the restoration, and controlling the milling process.

The potential risks associated with use of the 3-D scanning camera and laser scanner are minor and are similar to risks associated with the use of other Class I, exempt dental devices. The potential risks can be categorized as related to electrical safety, electromagnetic compatibility, cross-contamination, laser safety, and incorrect data resulting in a poorly fitting prosthesis.

Electrical Safety

The data acquisition devices are AC powered and, therefore the devices are designed in conformance with internationally recognized standards for electrical safety, such as IEC 60601 and UL 2601. However, there is only minimal risk to the patient because the patient has no direct contact with any of the electrical components of the device, except potentially with the 3-D camera when it is inserted into the patient's oral cavity for imaging. This same risk is inherent in other electrically powered dental devices such as intraoral dental drills (21 CFR 872.4130), fiberoptic dental lights (21 CFR 872.4620) and dental operative unit accessories (21 CFR 872.6640) that are classified in Class I and exempt from premarket notification.

Electromagnetic Compatibility

Because the devices are powered, they are also potentially susceptible to electromagnetic interference from other powered devices or from electrostatic discharge, or could potentially cause electromagnetic problems with other devices. For this reason the devices are manufactured in conformance with internationally recognized standards for electromagnetic compatibility, such as IEC 60601-1-2. However, there is no direct risk to the patient from this device due to issues of

electromagnetic compatibility. The only indirect risk is that the data from the acquisition unit could be distorted. Issues of electromagnetic compatibility pose no greater risk for use of data acquisition devices as compared with other powered Class I dental devices that are exempt from premarket notification

Cross-contamination

Because the scanning camera may be placed in the patient's mouth, it must be cleaned and disinfected between each use. Improper cleaning and disinfection could result in contamination of the patient or operator. This risk is similar to that for any dental device used in the oral cavity, including several Class I, exempt dental devices such as a dental X-ray film holder (21 CFR 872.1905), dental bur (21 CFR 3240), intraoral dental drill (21 CFR 872.4130) and fiberoptic dental light (21 CFR 872.4620). This risk is minimized by including adequate instructions for cleaning and disinfecting the scanning camera within the device labeling.

Laser Safety

Issues of laser safety are unique to laser scanning types of acquisition units. However, the patient is not exposed to the laser when the laser is in use. The laser scanner in the CEREC system is a low power (250 μW) 670 nm Class II laser diode. When installed in the milling unit, the protective housing reduces accessible emissions of the laser scanner to Class I levels as defined in 21 CFR 1040.10(b)(5). Risks to the operator associated with the laser scanner are minimized by conformance to the requirements of 21 CFR 1040, which include appropriate warnings and precautions in the labels and labeling and the safety interlock that causes the laser radiation to be disabled when the milling chamber door is open, thus preventing the operation of the laser scanner without the protective housing in place.

Incorrect Data

Data used to design and manufacture the dental restorations could potentially be incorrect due to hardware or software failures. The risk of hardware or software failures is minimized by manufacturing the device in conformance with FDA quality system regulations.

In addition, the data obtained by the acquisition device is displayed to the trained operator during the restoration design phase. Any missing or corrupted data would result in an image of the tooth that is visibly distorted. The only risk to the patient is that the scanning process would need to be repeated. There is also the risk that a poorly fitting prosthesis could result from a poor design or manufacturing process.

However, CAD-CAM systems for dental restoration are not regulated as medical devices. In addition, the resulting prosthesis is fitted by a trained dentist who can recognize the improper fit of the restoration. The only risk to the patient from a poor fit is that the restoration will need to be modified for a better fit or the process will need to be repeated.

The hazards discussed above are potential hazards associated with the devices. In actual clinical use, the risk profile for the devices is very low. In preparation for this reclassification petition, the petitioner reviewed its complaint files, the FDA MDR and MAUDE databases, and the published literature for reports of complications, injuries, or problems related to use of the CEREC Systems. The petitioner has received no complaints of injuries or malfunctions that could result in injuries, and no MDRs have been filed related to the CEREC Systems.

An initial search for English language articles using the PubMed search engine and the keyword "CEREC" resulted in more than 200 hits. The literature search was refined using the keywords "CEREC AND adverse events," "CEREC AND complications," "CEREC AND risks," and "CEREC AND injuries." Four articles were returned from this search, all of which are included in APPENDIX E. None of the articles report any injuries to the patients during the data acquisition phase of the restoration process. All of the articles report good results, even after four-year follow-up (Heymann et al., 1996). The only report of any problems relating to the CEREC restorations is contained in Sjögren et al., 1995. In this study of 66 CEREC inlays in 27 patients, six patients showed slight postoperative sensitivity related to one of their inlays. This lasted for a couple of days for two patients, 1 to 2 weeks for two patients, and longer term (12 and 24 months) for two patients. Pre-existing conditions in patients, described as clicking sensations from the TMJ, tenderness on palpation from the masticatory muscles and tooth wear, were not aggravated by the ceramic restorations. The authors concluded that the "CEREC restorations showed an almost ideal performance after 2 years."

The information available for the types of devices included in this reclassification petition, including the information in the CEREC 510(k)s, the analysis of potential hazards and the very low risk profile in actual dental practice, demonstrates that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of scanning devices for dental restoration CAD-CAM systems.

10. FINANCIAL CERTIFICATION/DISCLOSURE STATEMENTS

Financial certification/disclosure statements are not applicable to this reclassification petition because the petitioner is not relying on any clinical data to provide reasonable assurance of the safety and effectiveness of the dental data acquisition devices proposed for reclassification.